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510(k) Summary

AUG 2 8 2009

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: July 2, 2009

Submitter: GE Medical Systems Information Technologies

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Milwaukee, Wisconsin 53223 USA

Primary Contact Person: Joel Kent
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Secondary Contact Person: David Wahlig
Director, Regulatory Affairs
GE Healthcare
phone 414-362-3242

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Device: Trade Name: **CARESCAPE™ Monitor B850**

Common/Usual Name: multi-parameter patient monitor

Classification Names: 21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Product Code: MHX

Predicate Device(s): K071073: Solar 8000 and Transport Pro with Patient Data Module

K051400: Datex Ohmeda S/5 Anesthesia Monitor with L-ANE05 and L-ANE05A software

Device Description: The CARESCAPE Monitor B850 includes both new and existing subsystems interconnected to form a high acuity, multi-parameter patient monitoring system. A typical configuration would be a CARESCAPE Monitor B850 host processing unit running the CARESCAPE Monitoring platform software, a display with integrated keyboard and a frame for the insertion of parameter measurement modules. A variety of options are available to the customer including additional displays, various input devices (keyboard, mouse, bar code reader), additional modules and frames and software options.

The new subsystems include a host processing unit (CPU), a 15 inch LCD display with an integrated keypad, 19 inch LCD display with an integrated keypad and touch panel interface, a five slot parameter module frame, a seven slot parameter module frame, a cabled remote control, a cabled remote keypad, and the

CARESCAPE Monitoring platform software. Some of these new major subsystems include non-patient contact accessory items (e.g. cables and mounting hardware). The CARESCAPE Monitor B850 interfaces to a variety of existing physiological parameter measurement modules. In addition, the CARESCAPE Monitor B850 interfaces to a variety of existing OEM medical devices via the existing network infrastructure.

Intended Use:

The CARESCAPE™ Monitor B850 is a multi-parameter high acuity patient monitor intended for use in multiple areas within a professional healthcare facility.

The CARESCAPE Monitor B850 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time

The CARESCAPE Monitor B850 system is indicated for monitoring of Hemodynamic (including ECG, ST Segment, Arrhythmia Detection, ECG Diagnostic Analysis and Measurement, Invasive Pressure, Noninvasive Blood Pressure, Pulse Oximetry, Cardiac Output, Temperature, Impedance Respiration and SvO2 (Mixed Venous Oxygen Saturation)), Airway Gases (Fi/Et CO2, O2, N2O and Anesthetic Agent), Spirometry, Gas Exchange (O2 Consumption (VO2), CO2 production (VCO2), energy expenditure (EE), and respiratory quotient (RQ)) and neurophysiological (including electroencephalography (EEG), Entropy, Bispectral Index (BIS) and Neuromuscular Transmission (NMT) Monitoring) status.

The CARESCAPE Monitor B850 provides alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices. The CARESCAPE Monitor B850 can be a stand-alone monitor or interfaced to other devices. It can also be connected to other monitors for bed to bed viewing and to data management software devices via a network.

The CARESCAPE Monitor B850 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility. In addition to the healthcare practitioner, the CARESCAPE Monitor B850 is designed to provide configuration and troubleshooting capabilities to qualified service personnel.

The CARESCAPE Monitor B850 is not intended for use during MRI.

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Technology: The CARESCAPE Monitor B850 is a new monitor that essentially is a combination of the features and parameters of two existing predicate monitor platforms. The predicate Solar 8000i V5 Patient Monitoring System (K071073) and the S/5 Anesthesia Monitor system (K051400). The fundamental technology of the CARESCAPE Monitor B850 is the same as the predicate devices.

The CARESCAPE Monitor B850 device is as safe and effective the predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The **CARESCAPE™ Monitor B850** and its applications comply with voluntary standards as detailed in this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, **CARESCAPE™ Monitor B850** did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the **CARESCAPE™ Monitor B850** to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 8 2009

GE Medical Systems Information Technogoies
c/o Mr. Joel Kent
Manager, Qaulity and Regulatory Affairs
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K092027
CARESCAPE™ Monitor B850
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: July 2, 2009
Received: July 6, 2009

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092027

Indications for Use

510(k) Number (if known): K092027

Device Name: **CARESCAPE™ Monitor B850**

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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